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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,024	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on application filed in Sweden on December 3, 2003. It is noted, however, that applicant has not filed a certified copy of the 0303270-3 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statement (IDS) submitted March 8, 2004 is improper, because it is not on a 1449 form and is merely a listing of the instant application and copending applications by the same inventor. The Examiner respectfully suggests submitting a 1449 form, wherein the pre-grant publication number of copending applications 10/703,505, 10/603,819, 10/603,818, and 10/729, 024 are provided.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The use of the trademarks SPIRIVA® (pg. 4, line 30; pg. 8, lines 4; pg. 13, lines 13, 27, and Table 1), HANDIHALER® (pg. 5, line 1; pg. 13, lines 26 and Table 1), and RESPIMAT® (pg. 2, line 32; pg. 3, lines 1, 3, and 12) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high" in claims 1 and 7 is a relative term, which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is noted that the terms "high barrier seal" is defined on page 8 of the instant specification. Whereas this definition appears to adequately define what a barrier seal is, it is insufficient to define the intended meaning of the word "high." This definition utilizes the relative term "high," and is therefore inherently indefinite. It would not be clear to a person of ordinary skill in the art what the term "high" is intended to mean, as it

requires comparison with something else to ascertain what is intended. For example, it is unclear whether a high barrier to moisture is intended to mean that only a certain percentage of moisture content, such as 1% moisture, may seep into the composition within a given time period.

The term "gradually" in claims 2 and 9 is a relative term, which renders the claim indefinite. The term "gradually" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "gradually" is a relative reference to a rate; however, a person of ordinary skill in the art would not be able to ascertain accurately what rates Applicant intended.

The remaining claims are rejected for depending upon a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US 2002/0053344) in view of Keller et al. (U.S. Patent No. 6,645,466) (USPN '466).

Davies teaches an **inhalation device for use with a medicament pack** in which at least **one container for medicament in powder form** is defined between two sheets peelably secured to one another (title and abstract).

Davies teaches that the medicament pack comprises an elongate strip formed from a base sheet having a plurality of recesses spaced along its length and a lid sheet **hermetically but peelably sealed** thereto **to define a plurality of containers**, **each container having therein inhalable medicament in powder form** [0006].

Davies teaches in [0041] and Figures 1, 2, and 3a to 3c that the strip (1) comprises a base sheet (3) in which **blisters** are formed to define the **pockets** (2), and a lid sheet (4) which is **hermetically sealed to the base sheet (3)** except in the region of the blisters, such a manner that the lid sheet and the base sheet can be peeled apart. The **lid and base sheets are each preferably formed of a plastics/aluminum laminate**, and the lid and base sheets are preferably adhered to one another by heat sealing. By way of example, the lid material may be a laminate

consisting of 50 gsm bleach kraftpaper/12 micron **polyester** (PETP) film/20 micron **soft temper aluminum foil**/9 gsm vinylic peelable heat seal lacquer (sealable to PVC), and the base material may be a **laminate** consisting of 100 micron **PVC/45 micron soft temper aluminum foil/25 micron orientated polyamide**. The lacquer of the lid material is sealed to the PVC layer of the base material to provide the peelable seal between the lid and base sheets. Polyester, polyamides, and PVC are polymers. The seal is defined between two members, **peelably secured to one another** [0004]. According to the Applicant's specification (pg. 7) blisters and capsules are included in the term "dose bed."

Davies teaches in [0053] that when the user inhales air is drawn into the mouthpiece not only through the air inlets 140 but also through the air inlets 121, and the air entering through the inlets 121 produces a swirling airflow which helps to distribute powder effectively within the airflow and reduce the extent to which powder is deposited on the inside of the mouthpiece. This also helps **to break up any aggregates of powder**, which may be present in the blister.

Davies teaches in [0071]-[0072] that the device is provided under a cover 491, which is pivotally mounted on the body 410 by means of a lug 492 on the body top 410b and a corresponding lug 493 on the body base 410a. The cover is pivotal between an open position (shown in FIG. 14) in which the mouthpiece is exposed and a closed position in which it is not, as is described more fully below. In operation, the user moves the cover 491 to its open position and then presses on the finger tab 482 of the lever 424 to cause it to move as the lever pivots. This makes the index ratchet wheel 422 rotate which, via the pawls 480, causes the index wheel 416 also to rotate. Rotation of the index wheel 416 produces rotation of both the base winding wheel 470 and the lid winding wheel 414, thus peeling the base sheet and lid sheet apart over a

distance sufficient to expose a previously unopened pocket 402 opposite the end of the powder outlet 419 in the manifold 486. The patient can then inhale through the mouthpiece, as in the preceding embodiments.

Davies teaches in [0091] that the medicament dispenser of his invention is suitable to dispensing medicament **for the treatment of COPD and asthma**.

Davies teaches in [0092] that suitable medicaments include **ketotifen (anti-allergic), fluticasone (anti-inflammatory steroid), budesonide (anti-inflammatory steroid), rofleponide (anti-inflammatory steroid), mometasone (anti-inflammatory steroid), ciclesonide (anti-inflammatory steroid), ipratropium (e.g. as bromide) (anticholinergic), tiotropium (anticholinergic), oxitropium (anticholinergic)** and where appropriate salts, esters, or solvates thereof.

Davies teaches in [0094] that suitable medicaments can also **be delivered in combinations**.

The hermetically sealed blister pack taught by Davies obviously constitutes a high barrier seal as part of a container. Although not identified as such, Davies' device obviously may be described as an air-razor device, because the suction created by a patient's inhalation produces a swirling airflow which helps to distribute powder effectively within the airflow, reduces the extent to which powder is deposited on the inside of the mouthpiece, and helps to break up any aggregates of powder.

Davies lacks the teaching of active agent fine particle fraction the bromide salt of tiotropium and oxitropium.

Keller teaches **dry powder formulations for inhalation**, containing a pharmaceutically ineffective carrier of not-inhalable particle size and a finely divided pharmaceutically active compound of inhalable particle size, wherein it was intended for said formulations to exhibit improved moisture resistance and storage stability. One of the features of the inventive dry powder is that **a high fine particle dosage or fine particle fraction** can be maintained also under relatively extreme temperature and humidity conditions (title and abstract).

Keller teaches that as active compound, the formulations obtainable according to the invention can preferably contain an **anticholinergic, such as tiotropium, ipratropium, and oxitropium** (col. 6, lines 13-19). The use of magnesium stearate is advantageous, in particular with dry powder formulations that contain at least one pharmaceutically active compound in the form of a pharmaceutically acceptable salt, including, **bromide** salts (col. 6, lines 40-44). Examples of pharmaceutically acceptable salts include, **oxitropium bromide, ipratropium bromide, and tiotropium bromide** (col. 6, lines 61-64).

Keller teaches that the **dry powder formulations** can be prepared according to the invention by mixing together a pharmaceutically inactive carrier of noninhalable particle size, a finely divided **pharmaceutically active compound of inhalable particle size**, for example having a **mean particle diameter of at most 10 microns (preferably at most 5 microns)**, and magnesium stearate (col. 8, lines 46-53).

Keller teaches in Examples 1-3 and Tables 1-3, inhalable pharmaceutical formulations having a fine particle fraction (FPF) between 30 % and 50 %. Example 6 presents an exemplary tiotropium formulation, which yields a **fine particle dose (FPD) of 8.0 micrograms** and a FPF of 48.4% after preparation.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Davies and Keller, because both inventors teach dry powder inhalation formulations and Davies teaches a dry powder inhaler. A skilled artisan would have been motivated to combine the teachings of Keller with those of Davies, because Keller's compositions exhibit improved stability and moisture resistance. A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success upon combination of the prior art teachings, because both references teach dry powder formulations comprising an anticholinergic and Davies' device is specifically designed to delivery a dry powder pharmaceutical formulation to a patient in need of treatment of a respiratory disorder, such as asthma and COPD.

The prior art references do not expressly recited the step of selecting a medicament, however, it would have been apparent to a skilled artisan that the disclosure of an active agent as suitable for use in the prior art teachings is equivalent to selecting a medicament. A skilled artisan would have had the requisite skill to appropriately select the correct active agent (e.g. anticholinergic) required for the treatment of a respiratory disorder such as asthma or COPD. Regarding the amount of active agent present in a given formulation, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed

parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/005344 A1) in view of Weers et al. (US 2002/0017295).

The teachings of Davies have been set forth above.

Davies lacks the teaching of active agent fine particle fraction the bromide salt of tiotropium and oxitropium.

Weers teaches phospholipid-containing particulate compositions and methods for **pulmonary administration via dry powder inhalers** [0002].

Weers defines "active agent" as an agent, drug, compound, composition of matter or mixture thereof which provides some diagnostic, prophylactic, or pharmacologic, often beneficial, effect, including different classes of drugs (for example, anti-inflammatories, drugs acting on the histamine system, and bronchodilators) [0018].

Weers teaches that the phospholipids can make up to 90-99.9% w/w of his invented compositions [0035] and the particulate compositions may comprise combinations of two or more active agents in a single species of particulate composition or individually in separate species of particulate compositions [0040].

Weers teaches that the compositions may comprise excipients, including biocompatible polymers [0042], **optional excipients** (coloring agents, taste masking agents, buffers, etc) [0043], and other excipients [0044].

Weers teaches that the medicament is formulated in a way such that it readily disperses into discrete particles with an **MMD preferably between 0.5-5 microns**, characterized by an **aerosol particle size preferably less than 5.0 microns**. The mass median aerodynamic diameters (MMAD) of the powders will **more preferably characteristically range from about 1.0-4.0 microns MMAD** [0046].

Weers teaches that the particulate compositions are preferably provided in a "**dry" state** [0051].

It would have been obvious to a person of ordinary skill in the art at the time of the instant application to combine the teachings of Davies and Weers, because both inventors teach compositions for inhalation. It is obvious that a skilled artisan cognizant of the teachings of Weers would be motivated to make particulate compositions for inhalation characterized by a fine particle fraction (FPF) of at least 30%-50%, because Weers teaches the desirability of particles having a MMAD ranging from 1-4 microns. FPF is the percentage of particles having a MMAD less than some desirable value (often ~ 5 microns). The Applicants do not define FPF, but merely suggest on page 2 of the instant specification that it is preferable for particles to have an aerodynamic size of less than 5 microns. Due to the similarities between the compositions taught by Davies and Weers and used in Davies' inhalation device, a skilled artisan would have had a reasonable expectation of successfully combining these teachings. Regarding to the use of the bromide salts of oxitropium and tiotropium, this would have been obvious to a skilled artisan cognizant of the teachings of Davies, wherein ipratropium bromide is disclosed, because all three anticholinergics are structurally similar, including an endocyclic quaternary amine moiety with a positive charge.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braithwaite (WO 00/74754) in view of Weers et al. (US 2002/0017295).

Braithwaite teaches a **medicament delivery device** comprising a medicament reservoir, a medicament delivery passage, and a **metering member adapted to transfer a measured dose of medicament** from the reservoir to the delivery passage, wherein said device is provided with a **moisture proof barrier** (i.e. high barrier seal). The medicament delivery device is especially **suited for use as an inhaler**. Braithwaite also teaches a method of **treating patients suffering from a respiratory disorder** (abstract).

Braithwaite teaches that the moisture proof barrier is preferentially a physical barrier as opposed to a chemical barrier (e.g. desiccant), although it is within in the scope of the his invention that **a desiccant may be included in addition to the moisture proof barrier if desirable** (pg. 2, lines 21-24).

Braithwaite teaches in one embodiment that the sealing means of the delivery device will comprise a resilient sealing member, which may comprise any conventionally known material, including **natural or synthetic rubber, silicon, or a PTFE (polytetrafluoroethylene) material** (pg. 3, lines 1-10 and 14-14). It is especially preferred that the inhaler used in Braithwaite's invention is a **dry powder inhaler (DPI)** (pg. 3, lines 22-23).

Braithwaite teaches that the metering member may comprise a frusto conical dispensing member with a corresponding **moisture resistant sleeve** (pg. 4, lines 15-16). The moisture resistant sleeve may comprise any known material, but is preferentially **a plastics material** (sentence bridging pages 4 and 5).

Braithwaite teaches that a variety of medicaments may be administered using the inhaler of his invention, including bronchodilators or other **anti-asthma drugs** (sentence bridging pages 6-7). Specific drugs include, formoterol (beta2-agonist), salbutamol (beta2-agonist), salmeterol (beta2-agonist), **ipratropium bromide** (**anticholinergic**), etc. (pg. 7, lines 2-8). Ipratropium bromide is an anticholinergic drug, which has a chemical structure very similar to tiotropium.

Braithwaite teaches **a method of treatment of a patient with a respiratory disorder**, which comprises the administration of a combination of medicaments using an inhaler (pg. 7, lines 17-20).

Braithwaite lacks the teaching of FPF.

The teachings of Weers have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Braithwaite and Weers, because both inventors teach powder compositions for inhalation administration. A person of ordinary skill would have been motivated to combine the teachings of Braithwaite and Weers to ensure the stability of powdered pharmaceutical compositions contained within inhalers, especially ones comprising a moisture sensitive anticholinergic, and to minimize the chemical degradation resulting from the ingress of moisture to the anticholinergic-containing compositions. Regarding the anticholinergic disclosed by Braithwaite, it would have been apparent to a skilled artisan that one could substitute a compound from a class of active agents (e.g. anticholinergic) for a different compound from the same class of active agents, because both compounds would be expected to have the same general physiological effect. This would have been especially apparent in the case of structurally similar compounds from the same class of drugs, such as the anticholinergics,

ipratropium, oxitropium, and tiotropium. Therefore, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success upon combination of the teachings of Braithwaite and Weers and upon the substitution of ipratropium bromide for another known structurally similar anticholinergic, including tiotropium bromide and oxitropium bromide. Regarding the dosage amount of active agent and excipients taught in the prior art, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results (e.g. therapeutically effective amounts of active agents). Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,881,398 (USPN '398). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. Both claim 1 of the instant application and USPN '398 recite methods of administering a medication, comprising the step of depositing the active onto a substrate (e.g. dose bed), which is part of an inhalation device (e.g. inhaler) and having a subject inhale the medicament. The inhaled powder composition in both the instant application and UPSN '398 recite overlapping fine particle fractions (FPF): 30-50% is recited in the instant application and 50% is recited in USPN '398. It is noted that the instant application does not define FPF. The Examiner has interpreted the FPF limitation in claim 1 of the instant application as encompassing the definition of FPF recited in claim 1 of USPN '398. The instant application refers to the inhaler device being provided with an "Air-razor device," which the Examiner has interpreted as meaning an inhaler with a configuration resulting and/or device property, which leads to the de-aggregation of the active formulation upon inhalation. USPN '398 recites the release of de-aggregated particles from the device utilized in the method of claim 1. Therefore, the Examiner concludes that claim 1 of the instant application is *prima facie* obvious over claim 1 of USPN '398.

Claims 7-12 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/603,819 (copending '819) in view of Akehurst et al. (U.S. Patent No. 6,303,103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. . The claims of the instant application comprise an anticholinergic, which may be tiotropium bromide, ipratropium bromide, or oxitropium bromide. The difference between claims 7-12 of instant application and claims 12-14 and 16-22 of copending '986 is that the independent composition claim (i.e. claim 7) of the instant application is generically drawn to a composition comprising an anticholinergic. Subsequent dependent claims of the instant application identify the anticholinergic as ipratropium bromide (claim 10 of instant), tiotropium bromide (claim 11 of instant), and oxitropium bromide (claim 12 of instant). Both ipratropium bromide and oxitropium bromide are anticholinergics that have similar chemical structures relative to the chemical structure of tiotropium. Regarding the recited methods of administration (claims 1-6 of the instant application and 1-10 of copending '819), both claim sets recite similar steps of dosage preparation and inhalation from a dry powder inhaler to a user inhaling once. The step of selecting a medicament is implicit in copending '819. Difference between these applications include: (a) copending '819 recites a dry powder composition comprising two medicaments, wherein the term medicament reads on all known active agents, including anticholinergics and (b) copending '819 recites in claims 7 and 12 that the active agent is pure. The use of a pure active agent would have been obvious to a person of ordinary skill in the art at the time of the instant invention, because high active agent purity would facilitate accurate dosing upon

administration. The deficiency of the instant application regarding the teaching of a formulation comprising two medicaments is cured by the teachings of Akehurst et al. Akehurst states that aerosol compositions containing two active agents are known for the treatment of respiratory disorders, such as asthma (col. 3, lines 31-34). Akehurst also identifies two anticholinergics, which are suitably combined with salmeterol: ipratropium and oxitropium (col. 3, lines 56-57). The Examiner concludes that claims 1-12 of the instant application are *prima facie* obvious over claims 1-20 of copending '819.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-12 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 and 16-22 of copending Application No. 10/728,986 (copending '986). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. No weight has been given to the limitations of the composition containers of the cited claims of the instant application, the intended use of a composition in either application in this comparative analysis. The claims of the instant application comprise an anticholinergic, which is tiotropium bromide, ipratropium bromide, or oxitropium bromide. The difference between claims 7-12 of instant application and claims 12-14 and 16-22 of copending '986 is that the independent composition claim (i.e. claim 7) of the instant application is generically drawn to a composition comprising an anticholinergic. Subsequent dependent claims of the instant application identify the anticholinergic as ipratropium bromide (claim 10 of instant), tiotropium bromide (claim 11 of instant), and

oxitropium bromide (claim 12 of instant). Both ipratropium bromide and oxitropium bromide are anticholinergics that have similar chemical structures relative to the chemical structure of tiotropium.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The specification is objected. Claims 1-12 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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